TENT COOPERATION TRE Y

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

Åkerman, Mårten
Albihns Malmö AB
P.O. Box 4289
S-203 14 Malmö
SUÈDE

Date of mailing (day/month/year)
16 janvier 2002 (16.01.02)

Applicant's or agent's file reference
P11181-M/MIK

IMPORTANT NOTIFICATION

International application No.
PCT/EP00/08207

International filing date (day/month/year)
21 août 2000 (21.08.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
CEFAR PAINMATCHER AB
Scheelevägen 32
S-223 63 Lund
Sweden

State of Nationality: SE
State of Residence: SE
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [X] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address
PAINMATCHER AB
Scheelevägen 32
S-223 63 Lund
Sweden

State of Nationality: SE
State of Residence: SE
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
Catherine MASSETTI
Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

Åkerman, Mårten
Albihns _Malmö AB
P.O. Box 4289
S-203 14 Malmö
SUÈDE

Date of mailing (day/month/year) 02 May 2001 (02.05.01)	
Applicant's or agent's file reference P11181-M/MIK	**IMPORTANT NOTIFICATION**
International application No. PCT/EP00/08207	**International filing date** (day/month/year) 21 August 2000 (21.08.00)

1. The following indications appeared on record concerning:

[ ] the applicant [ ] the inventor [X] the agent [ ] the common representative

Name and Address	State of Nationality	State of Residence
BERGMAN, Kerstin Albihns Patentbyrå_Malmö AB P.O. Box 4289 S-203 14 Malmö Sweden		
	Telephone No. +46-40-690 54 00	
	Facsimile No. +46-40-611 96 89	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [X] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address	State of Nationality	State of Residence
Åkerman, Mårten Albihns _Malmö AB P.O. Box 4289 S-203 14 Malmö Sweden		
	Telephone No. +46-40-690 54 00	
	Facsimile No. +46-40-611 96 89	
	Teleprinter No.	

3. Further observations, if necessary:
The indication of a new company's name of the aget on the Demand (Form PCT/IPEA/401) has been considered a request for recording a change under Rule 92bis. In case of disagreement, the International Bureau should be notified immediately.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Claudio Borton
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

AKERMAN, Marten
ALBIHNS MALMÖ AB
P.O. Box 4289
SE-203 14 Malmö
SUEDE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	05.12.2001
Applicant's or agent's file reference: P11181-M/MIK	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/08207	21/08/2000	20/08/1999

Applicant: CEFAR PAINMATCHER AB et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Marra, E Tel.+49 89 2399-7235

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P11181-M/MIK		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/08207	21/08/2000	20/08/1999
International Patent Classification (IPC) or national classification and IPC A61B5/103		
Applicant CEFAR PAINMATCHER AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10/03/2001	05.12.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Abraham, V Telephone No. +49 89 2399 7463

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/08207

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-13 as originally filed

Claims, No.:

1-50 with telefax of 20/11/2001

Drawings, sheets:

1/2,2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 24-50.

because:

☒ the said international application, or the said claims Nos. 24-50 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-23

	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-23
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-23
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Reference is made to the following document:
D1: US-A-5 191 896 (E. GAFNI ET AL.) 9 March 1993
D2: WO 97 06730 A (J. KATIMS) 27 February 1997

III

1. According to Article 34(4)(a)(i) PCT and Rule 67.1 PCT no international preliminary examination is required to be carried out on claims 24-50 of the present application, because the subject-matter of these claims relates to a diagnostic method practised on the human body.

V

1. Document D2 which is considered to represent the most relevant prior art discloses the following features of claim 1, as far as this claim is understood (see paragraph VIII below):

   A sensation level (Fig. 2) measuring device comprising a stimulator devised to deliver a physical stimulus comprising:
   an indication mechanism (101), that is actuateable by the person,
   a level registration means (102),
   means for delivering the physical stimulus as a pulsating stimulus having a predetermined frequency (page 10, line 32 - page 11, line 9).

   The subject-matter of claim 1 differs from D1 in that the device further comprises means for varying the pulse width while for a predetermined period of time maintaining the predetermined frequency.

   The problem to be solved by the present invention is to provide a stimulus for selectively stimulating the C-fibres of human tissue which are regarded as being responsible for carrying an affective component of a sensation.

   In D2 different nerve fibres are stimulated by varying the frequency of the pulsating stimulus (page 15, lines 1-6). No indication can be found in this document to modulate the pulse width in order to solve the above problem. Document D1 discloses a sensation level measuring device comprising a pulse width modulation circuit (column 3, line 9). However, D1 does not define a

pulsating stimulus and the pulse width in D1 is the duration of the physical stimulus corresponding to the predetermined period of time defined in claim 1. All other prior art documents also give no indication for a pulsating stimulus having a predetermined frequency wherein the pulse width of the pulsating stimulus is varied. The combination of features of claim 1 as far as being understood is therefore neither known from, nor rendered obvious by, the available prior art and the requirements of Article 33(2)-(4) are met.

1.2 Claims 2-23 dependent on claim 1 amended as indicated below (see paragraph VIII 1.1) would also meet the requirements of Article 33(2)-(4) PCT.

VII

1. The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

2. According to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 should have been mentioned in the description and these documents should have been identified therein.

3. Not all examination authorities accept the formulation "*incorporated herein by reference*" used in the present application on page 1, line 32.

VIII

1. Claim 1 relates to a sensation level **measuring** device but the feature defining the measuring properties (i.e. means for varying the pulse width for the purpose of comparing said physical stimulus with an affective component of said sensation) is entirely unclear contrary to the requirements of Article 6 PCT..

It is obvious from the description that in order to measure a sensation level the patient must indicate a sensation, the stimulation parameters of which are then registered for evaluation purposes. The corresponding features, namely an indication mechanism, that is actuateable by the person and a level registration means, are therefore regarded as being essential to the definition of a sensation level **measuring** device and should have been inserted in claim 1 in order to overcome the above clarity objection.

1.1 For the assessment given in paragraph V above it is assumed that these features have been inserted in claim 1.

PCT/EP00/08207

Amendments in response to telephone communication 05/11/2001

Claims

1. A sensation level measuring device comprising a stimulator devised to deliver a physical stimulus, **characterized in**
- means for delivering said physical stimulus as a pulsating stimulus having a predetermined frequency;
- means for varying the pulse width while for a predetermined period of time maintaining said predetermined frequency of said pulsating stimulus for the purpose of comparing said physical stimulus with an affective component of said sensation.

2. The measuring device as recited in claim 1, wherein said predetermined frequency is fixed, and said pulse width is varied while maintaining a fixed amplitude.

3. The measuring device as recited in claim 1 or 2, wherein said stimulator is further devised to vary the amplitude of said pulsating physical stimulus for the purpose of comparing said physical stimulus with a sensory component of said sensation.

4. The measuring device as recited in claim 3, wherein said stimulator devised to selectively deliver a first physical stimulus having said varied pulse width or a second physical stimulus having said varied amplitude, for the purpose of separating an affective component from a sensory component of said measured sensation.

5. The measuring device as recited in claim 4, wherein the physical stimulus is achieved by means of delivering electrical energy to the skin of a human being.

6. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the pulse width of said physical stimulus being delivered in the shape of a pulsating electrical energy wave in the range of 0-1000 microseconds.

7. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the pulse width of said physical stimulus being delivered in the shape of a pulsating electrical energy wave with steps in the range of 5-10 microseconds.

8. The measuring device as recited in claim 5, wherein said electrical energy is voltage controlled.

9. The measuring device as recited in claim 5, wherein said electrical energy is current

AMENDED SHEET

controlled.

10. The measuring device as recited in claim 5, wherein said stimulator is capable of delivering electrical energy in the shape of a voltage or a current through a resistance of 0-20 kohm.

11. The measuring device as recited in claim 5, wherein said stimulator is capable of delivering said electrical energy in the shape of a voltage or a current in a square wave and/or a triangular wave, preferably having a frequency in the range of 1-100 Hz.

12. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the amplitude of a pulsating electrical current in the range of 0-100 mA.

13. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the amplitude of a pulsating electrical current with steps in the range of 0,5 mA.

14. The measuring device as recited in claim 1, 2, 3 or 4 wherein the physical stimulus is achieved by exchanging energy with or inducing thermal energy into the skin of a human being.

15. The measuring device as recited in claim 14, wherein the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

16. The measuring device as recited in claim 14, wherein the stimulator is capable of delivering a pulsating thermal energy exchange or induction stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds.

17. The measuring device as recited in claim 14, wherein the physical stimulus is achieved by means of delivering heat or radiation energy to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades.

18. The measuring device as recited in claim 14, wherein the stimulator is devised to vary the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in

the range of 10 to 60 seconds.

19. The measuring device as recited in claim 14, wherein the physical stimulus is achieved by means of cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades.

20. The measuring device as recited in claim 14, wherein the stimulator is devised to vary the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

21. The measuring device as recited in claim 14, comprising a resistive coil or a peltier element.

22. The measuring device as recited in claim 14, comprising a laser, such as an argon laser or a carbon dioxide laser.

23. The measuring device as recited in claim 1, 2, 3 or 4 wherein:
-said stimulator comprises a stimulus signal generator (102) coupled to stimulus induction means (104) for inducing a pulsating physical stimulus to said person; and the measuring device further comprising
-an indication mechanism (124), that is actuateable by said person, for indicating that a stimulus is experienced by the person to correspond to the level of said sensation;
-a level registration means (114,116) for registering a sensation level value corresponding to said sensation, and
- means (122) for varying the pulse width of the physical stimulus with a constant predetermined frequency and a constant amplitude for the purpose of measuring the level of an affective component of said sensation.

24. Use of an apparatus as recited in any of the claims 1-23 in measuring the level of a sensation.

25. Use of an apparatus as recited in any of the claims 1-23 in measuring the level of a perception.

26. Use of an apparatus as recited in any of the claims 1-23 in measuring the level of an integrated skill.

27. A method of measuring the level of a sensation, perception or integrated skill of a person, characterized in the steps of:
delivering to said person a pulse width modulated pulsating physical stimulus for comparing with an affective component of said sensation;
registering a first sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation.

28. The method as recited in claim 27, further comprising the step of varying the pulse width of the pulsating physical stimulus in the range of 0-1000 microseconds.

29. The method as recited in claim 27, further comprising the step of delivering a pulsating physical stimulus with a varying pulse width, a fixed frequency and a fixed amplitude.

30. The method as recited in claim 27, further comprising the step of delivering a physical stimulus that is comparable with a sensory component of said sensation.

31. The method as recited in claim 27, further comprising the step of delivering an amplitude modulated pulsating physical stimulus.

32. The method as recited in claim 27, further comprising the step of achieving the physical stimulus by delivering electrical energy to the skin of a human being.

33. The method as recited in claim 32, wherein said electrical energy is voltage controlled.

34. The method as recited in claim 32, wherein said electrical energy is current controlled.

35. The method as recited in claim 32, further comprising the step of delivering electrical energy in the shape of a voltage or a current through a resistance of 0-20 kohm.

36. The method as recited in claim 32, further comprising the step of delivering electrical energy in the shape of a voltage or a current in a sinus wave, preferably having a frequency in the range of 1-100 Hz.

37. The method as recited in claim 32, further comprising the step of delivering a electrical energy in the shape of a voltage or a current in a square wave and/or a triangular wave, preferably having a frequency in the range of 1-100 Hz.

38. The method as recited in claim 32, further comprising the step of varying the amplitude of a pulsating electrical current in the range of 0-100 mA.

AMENDED SHEET

39. The method as recited in claim 32, further comprising the step of varying the amplitude of a pulsating electrical current with steps in the range of 0,5 mA.

40. The method as recited in claim 32, further comprising the step of varying the pulse width of a pulsating electrical energy wave in the range of 0-1000 microseconds.

41. The method as recited in claim 32, further comprising the step of varying the pulse width of a pulsating electrical energy wave with steps in the range of 5-10 microseconds.

42. The method as recited in claim 27, further comprising the step of achieving the physical stimulus by exchanging thermal energy with or inducing thermal energy into the skin of a human being.

43. The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a sinus wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

44. The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

45. The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds.

46. The method as recited in claim 42, further comprising the step of achieving the physical stimulus by delivering heat to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades.

47. The method as recited in claim 46, further comprising the step of varying the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in the range of 10 to 60 seconds.

48. The method as recited in claim 42, further comprising the step of achieving the

physical stimulus by cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades.

49. The method as recited in claim 48, further comprising the step of varying the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

50. The method as recited in claim 27, for measuring the level of a sensation, perception or integrated skill of a person, comprising the steps of:
selectively delivering to said person a first physical stimulus that is comparable with an affective component of said sensation or a second physical stimulus that is comparable with a sensory component of said sensation;
registering a sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation;
indicating whether the registered sensation level value is based on said first physical stimulus or said second physical stimulus respectively.

14

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P11181-M/MIK		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/08207	21/08/2000	20/08/1999
International Patent Classification (IPC) or national classification and IPC A61B5/103		
Applicant CEFAR PAINMATCHER AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10/03/2001	05.12.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Abraham, V Telephone No. +49 89 2399 7463

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/08207

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-13 as originally filed

Claims, No.:

1-50 with telefax of 20/11/2001

Drawings, sheets:

1/2,2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 24-50.

because:

☒ the said international application, or the said claims Nos. 24-50 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-23

	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-23
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-23
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Reference is made to the following document:
D1: US-A-5 191 896 (E. GAFNI ET AL.) 9 March 1993
D2: WO 97 06730 A (J. KATIMS) 27 February 1997

III

1. According to Article 34(4)(a)(i) PCT and Rule 67.1 PCT no international preliminary examination is required to be carried out on claims 24-50 of the present application, because the subject-matter of these claims relates to a diagnostic method practised on the human body.

V

1. Document D2 which is considered to represent the most relevant prior art discloses the following features of claim 1, as far as this claim is understood (see paragraph VIII below):

   A sensation level (Fig. 2) measuring device comprising a stimulator devised to deliver a physical stimulus comprising:
   an indication mechanism (101), that is actuateable by the person,
   a level registration means (102),
   means for delivering the physical stimulus as a pulsating stimulus having a predetermined frequency (page 10, line 32 - page 11, line 9).

   The subject-matter of claim 1 differs from D1 in that the device further comprises means for varying the pulse width while for a predetermined period of time maintaining the predetermined frequency.

   The problem to be solved by the present invention is to provide a stimulus for selectively stimulating the C-fibres of human tissue which are regarded as being responsible for carrying an affective component of a sensation.

   In D2 different nerve fibres are stimulated by varying the frequency of the pulsating stimulus (page 15, lines 1-6). No indication can be found in this document to modulate the pulse width in order to solve the above problem. Document D1 discloses a sensation level measuring device comprising a pulse width modulation circuit (column 3, line 9). However, D1 does not define a

pulsating stimulus and the pulse width in D1 is the duration of the physical stimulus corresponding to the predetermined period of time defined in claim 1. All other prior art documents also give no indication for a pulsating stimulus having a predetermined frequency wherein the pulse width of the pulsating stimulus is varied. The combination of features of claim 1 as far as being understood is therefore neither known from, nor rendered obvious by, the available prior art and the requirements of Article 33(2)-(4) are met.

1.2 Claims 2-23 dependent on claim 1 amended as indicated below (see paragraph VIII 1.1) would also meet the requirements of Article 33(2)-(4) PCT.

VII

1. The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

2. According to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 should have been mentioned in the description and these documents should have been identified therein.

3. Not all examination authorities accept the formulation "*incorporated herein by reference*" used in the present application on page 1, line 32.

VIII

1. Claim 1 relates to a sensation level **measuring** device but the feature defining the measuring properties (i.e. means for varying the pulse width for the purpose of comparing said physical stimulus with an affective component of said sensation) is entirely unclear contrary to the requirements of Article 6 PCT..

   It is obvious from the description that in order to measure a sensation level the patient must indicate a sensation, the stimulation parameters of which are then registered for evaluation purposes. The corresponding features, namely an indication mechanism, that is actuateable by the person and a level registration means, are therefore regarded as being essential to the definition of a sensation level **measuring** device and should have been inserted in claim 1 in order to overcome the above clarity objection.

1.1 For the assessment given in paragraph V above it is assumed that these features have been inserted in claim 1.

PCT/EP00/08207

Amendments in response to telephone communication 05/11/2001

Claims

1. A sensation level measuring device comprising a stimulator devised to deliver a physical stimulus, **characterized in**
- means for delivering said physical stimulus as a pulsating stimulus having a predetermined frequency;
- means for varying the pulse width while for a predetermined period of time maintaining said predetermined frequency of said pulsating stimulus for the purpose of comparing said physical stimulus with an affective component of said sensation.

2. The measuring device as recited in claim 1, wherein said predetermined frequency is fixed, and said pulse width is varied while maintaining a fixed amplitude.

3. The measuring device as recited in claim 1 or 2, wherein said stimulator is further devised to vary the amplitude of said pulsating physical stimulus for the purpose of comparing said physical stimulus with a sensory component of said sensation.

4. The measuring device as recited in claim 3, wherein said stimulator devised to selectively deliver a first physical stimulus having said varied pulse width or a second physical stimulus having said varied amplitude, for the purpose of separating an affective component from a sensory component of said measured sensation.

5. The measuring device as recited in claim 4, wherein the physical stimulus is achieved by means of delivering electrical energy to the skin of a human being.

6. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the pulse width of said physical stimulus being delivered in the shape of a pulsating electrical energy wave in the range of 0-1000 microseconds.

7. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the pulse width of said physical stimulus being delivered in the shape of a pulsating electrical energy wave with steps in the range of 5-10 microseconds.

8. The measuring device as recited in claim 5, wherein said electrical energy is voltage controlled.

9. The measuring device as recited in claim 5, wherein said electrical energy is current

controlled.

10. The measuring device as recited in claim 5, wherein said stimulator is capable of delivering electrical energy in the shape of a voltage or a current through a resistance of 0-20 kohm.

11. The measuring device as recited in claim 5, wherein said stimulator is capable of delivering said electrical energy in the shape of a voltage or a current in a square wave and/or a triangular wave, preferably having a frequency in the range of 1-100 Hz.

12. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the amplitude of a pulsating electrical current in the range of 0-100 mA.

13. The measuring device as recited in claim 5, wherein said stimulator is capable of varying the amplitude of a pulsating electrical current with steps in the range of 0,5 mA.

14. The measuring device as recited in claim 1, 2, 3 or 4 wherein the physical stimulus is achieved by exchanging energy with or inducing thermal energy into the skin of a human being.

15. The measuring device as recited in claim 14, wherein the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

16. The measuring device as recited in claim 14, wherein the stimulator is capable of delivering a pulsating thermal energy exchange or induction stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds.

17. The measuring device as recited in claim 14, wherein the physical stimulus is achieved by means of delivering heat or radiation energy to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades.

18. The measuring device as recited in claim 14, wherein the stimulator is devised to vary the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in

the range of 10 to 60 seconds.

19. The measuring device as recited in claim 14, wherein the physical stimulus is achieved by means of cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades.

20. The measuring device as recited in claim 14, wherein the stimulator is devised to vary the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

21. The measuring device as recited in claim 14, comprising a resistive coil or a peltier element.

22. The measuring device as recited in claim 14, comprising a laser, such as an argon laser or a carbon dioxide laser.

23. The measuring device as recited in claim 1, 2, 3 or 4 wherein:
-said stimulator comprises a stimulus signal generator (102) coupled to stimulus induction means (104) for inducing a pulsating physical stimulus to said person; and
the measuring device further comprising
-an indication mechanism (124), that is actuateable by said person, for indicating that a stimulus is experienced by the person to correspond to the level of said sensation;
-a level registration means (114,116) for registering a sensation level value corresponding to said sensation, and
- means (122) for varying the pulse width of the physical stimulus with a constant predetermined frequency and a constant amplitude for the purpose of measuring the level of an affective component of said sensation.

24. Use of an apparatus as recited in any of the claims 1-23 in measuring the level of a sensation.

25. Use of an apparatus as recited in any of the claims 1-23 in measuring the level of a perception.

26. Use of an apparatus as recited in any of the claims 1-23 in measuring the level of an integrated skill.

27. A method of measuring the level of a sensation, perception or integrated skill of a person, characterized in the steps of:
delivering to said person a pulse width modulated pulsating physical stimulus for comparing with an affective component of said sensation;
registering a first sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation.

28. The method as recited in claim 27, further comprising the step of varying the pulse width of the pulsating physical stimulus in the range of 0-1000 microseconds.

29. The method as recited in claim 27, further comprising the step of delivering a pulsating physical stimulus with a varying pulse width, a fixed frequency and a fixed amplitude.

30. The method as recited in claim 27, further comprising the step of delivering a physical stimulus that is comparable with a sensory component of said sensation.

31. The method as recited in claim 27, further comprising the step of delivering an amplitude modulated pulsating physical stimulus.

32. The method as recited in claim 27, further comprising the step of achieving the physical stimulus by delivering electrical energy to the skin of a human being.

33. The method as recited in claim 32, wherein said electrical energy is voltage controlled.

34. The method as recited in claim 32, wherein said electrical energy is current controlled.

35. The method as recited in claim 32, further comprising the step of delivering electrical energy in the shape of a voltage or a current through a resistance of 0-20 kohm.

36. The method as recited in claim 32, further comprising the step of delivering electrical energy in the shape of a voltage or a current in a sinus wave, preferably having a frequency in the range of 1-100 Hz.

37. The method as recited in claim 32, further comprising the step of delivering a electrical energy in the shape of a voltage or a current in a square wave and/or a triangular wave, preferably having a frequency in the range of 1-100 Hz.

38. The method as recited in claim 32, further comprising the step of varying the amplitude of a pulsating electrical current in the range of 0-100 mA.

39. The method as recited in claim 32, further comprising the step of varying the amplitude of a pulsating electrical current with steps in the range of 0,5 mA.

40. The method as recited in claim 32, further comprising the step of varying the pulse width of a pulsating electrical energy wave in the range of 0-1000 microseconds.

41. The method as recited in claim 32, further comprising the step of varying the pulse width of a pulsating electrical energy wave with steps in the range of 5-10 microseconds.

42. The method as recited in claim 27, further comprising the step of achieving the physical stimulus by exchanging thermal energy with or inducing thermal energy into the skin of a human being.

43. The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a sinus wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

44. The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

45. The method as recited in claim 42, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds.

46. The method as recited in claim 42, further comprising the step of achieving the physical stimulus by delivering heat to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades.

47. The method as recited in claim 46, further comprising the step of varying the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in the range of 10 to 60 seconds.

48. The method as recited in claim 42, further comprising the step of achieving the

physical stimulus by cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades.

49. The method as recited in claim 48, further comprising the step of varying the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

50. The method as recited in claim 27, for measuring the level of a sensation, perception or integrated skill of a person, comprising the steps of:
selectively delivering to said person a first physical stimulus that is comparable with an affective component of said sensation or a second physical stimulus that is comparable with a sensory component of said sensation;
registering a sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation;
indicating whether the registered sensation level value is based on said first physical stimulus or said second physical stimulus respectively.

PATENT COOPERATION TREATY

2001 -12- 10

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

AKERMAN, Marten
ALBIHNS MALMÖ AB
P.O. Box 4289
SE-203 14 Malmö
SUEDE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	05.12.2001
Applicant's or agent's file reference: P11181-M/MIK	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/08207	21/08/2000	20/08/1999

Applicant: CEFAR PAINMATCHER AB et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Marra, E Tel.+49 89 2399-7235

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P11181-M/MIK		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/08207	21/08/2000	20/08/1999
International Patent Classification (IPC) or national classification and IPC A61B5/103		
Applicant CEFAR PAINMATCHER AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10/03/2001	05.12.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Abraham, V Telephone No. +49 89 2399 7463

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/08207

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-13	as originally filed

Claims, No.:

1-50	with telefax of	20/11/2001

Drawings, sheets:

1/2,2/2	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 24-50.

because:

☒ the said international application, or the said claims Nos. 24-50 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-23

	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-23
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-23
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Reference is made to the following document:
D1: US-A-5 191 896 (E. GAFNI ET AL.) 9 March 1993
D2: WO 97 06730 A (J. KATIMS) 27 February 1997

III

1. According to Article 34(4)(a)(i) PCT and Rule 67.1 PCT no international preliminary examination is required to be carried out on claims 24-50 of the present application, because the subject-matter of these claims relates to a diagnostic method practised on the human body.

V

1. Document D2 which is considered to represent the most relevant prior art discloses the following features of claim 1, as far as this claim is understood (see paragraph VIII below):

A sensation level (Fig. 2) measuring device comprising a stimulator devised to deliver a physical stimulus comprising:
an indication mechanism (101), that is actuateable by the person,
a level registration means (102),
means for delivering the physical stimulus as a pulsating stimulus having a predetermined frequency (page 10, line 32 - page 11, line 9).

The subject-matter of claim 1 differs from D1 in that the device further comprises means for varying the pulse width while for a predetermined period of time maintaining the predetermined frequency.

The problem to be solved by the present invention is to provide a stimulus for selectively stimulating the C-fibres of human tissue which are regarded as being responsible for carrying an affective component of a sensation.

In D2 different nerve fibres are stimulated by varying the frequency of the pulsating stimulus (page 15, lines 1-6). No indication can be found in this document to modulate the pulse width in order to solve the above problem. Document D1 discloses a sensation level measuring device comprising a pulse width modulation circuit (column 3, line 9). However, D1 does not define a

pulsating stimulus and the pulse width in D1 is the duration of the physical stimulus corresponding to the predetermined period of time defined in claim 1. All other prior art documents also give no indication for a pulsating stimulus having a predetermined frequency wherein the pulse width of the pulsating stimulus is varied. The combination of features of claim 1 as far as being understood is therefore neither known from, nor rendered obvious by, the available prior art and the requirements of Article 33(2)-(4) are met.

1.2 Claims 2-23 dependent on claim 1 amended as indicated below (see paragraph VIII 1.1) would also meet the requirements of Article 33(2)-(4) PCT.

VII

1. The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

2. According to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 should have been mentioned in the description and these documents should have been identified therein.

3. Not all examination authorities accept the formulation "*incorporated herein by reference*" used in the present application on page 1, line 32.

VIII

1. Claim 1 relates to a sensation level **measuring** device but the feature defining the measuring properties (i.e. means for varying the pulse width for the purpose of comparing said physical stimulus with an affective component of said sensation) is entirely unclear contrary to the requirements of Article 6 PCT..

It is obvious from the description that in order to measure a sensation level the patient must indicate a sensation, the stimulation parameters of which are then registered for evaluation purposes. The corresponding features, namely an indication mechanism, that is actuateable by the person and a level registration means, are therefore regarded as being essential to the definition of a sensation level **measuring** device and should have been inserted in claim 1 in order to overcome the above clarity objection.

1.1 For the assessment given in paragraph V above it is assumed that these features have been inserted in claim 1.

Claims

1. A sensation level measuring device comprising
a stimulator devised to deliver a physical stimulus that is comparable with an affective component of said sensation.

2. The measuring device as recited in claim 1, wherein said stimulator is devised to deliver a pulse width modulated pulsating physical stimulus.

3. The measuring device as recited in claim 1, wherein said stimulator is devised to deliver a pulsating physical stimulus with a varying pulse width, a fixed frequency and a fixed amplitude.

4. The measuring device as recited in claim 1, wherein said stimulator is devised to deliver a physical stimulus that is comparable with a sensory component of said sensation.

5. The measuring device as recited in claim 1, wherein said stimulator is devised to deliver an amplitude modulated pulsating physical stimulus.

6. The measuring device as recited in claim 1, wherein the physical stimulus is achieved by means of delivering electrical energy to the skin of a human being.

7. The measuring device as recited in claim 6, wherein said electrical energy is voltage controlled.

8. The measuring device as recited in claim 6, wherein said electrical energy is current controlled.

9. The measuring device as recited in claim 6, wherein said stimulator is capable of delivering electrical energy in the shape of a voltage or a current through a resistance of 0-20 kohm.

10. The measuring device as recited in claim 6, wherein said stimulator is capable of delivering electrical energy in the shape of a voltage or a current in a sinus wave, preferably having a frequency in the range of 1-100 Hz.

11. The measuring device as recited in claim 6, wherein said stimulator is capable of delivering electrical energy in the shape of a voltage or a current in a square wave

and/or a triangular wave, preferably having a frequency in the range of 1-100 Hz.

12. The measuring device as recited in claim 6, wherein said stimulator is capable of varying the amplitude of a pulsating electrical current in the range of 0-100 mA.

13. The measuring device as recited in claim 6, wherein said stimulator is capable of varying the amplitude of a pulsating electrical current with steps in the range of 0,5 mA.

14. The measuring device as recited in claim 6, wherein said stimulator is capable of varying the pulse width of a pulsating electrical energy wave in the range of 0-1000 microseconds.

15. The measuring device as recited in claim 6, wherein said stimulator is capable of varying the pulse width of a pulsating electrical energy wave with steps in the range of 5-10 microseconds.

16. The measuring device as recited in claim 1, wherein said stimulator is capable of delivering a pulsating physical stimulus with a variable increase rate.

17. The measuring device as recited in claim 16, wherein said stimulator is devised to deliver said physical stimulus at a first increase rate in a first measurement and at a second increase rate in a subsequent second measurement.

18. The measuring device as recited in claim 16, wherein said stimulator is devised to deliver said physical stimulus at a first increase rate within a first pulse width range in a first measurement and at a second increase rate within a second pulse width range in a subsequent second measurement.

19. The measuring device as recited in claim 16, wherein the increase of said physical stimulus is carried out within a selected time period in a predetermined range of time and said selected time period is different between every two measurements on the same measurement object.

20. The measuring device as recited in claim 18, wherein the pulse width increases from about 0 to about 250 microseconds within a first time period between 15 and 40 seconds in said first increase rate, and from about 251 to about 500 microseconds within a second time period between 15 and 40 seconds selected to be different from said first time period.

21. The measuring de[redacted]as recited in claim 16, wherein said [redacted]ulator is devised to deliver said physical stimulus at a first increase rate within a first amplitude range in a first measurement and at a second increase rate within a second amplitude range in a subsequent second measurement.

22. The measuring device as recited in claim 21, wherein said first and second amplitude ranges are different selections from the range of 0-100 mA, and said first and second increase rates are based on different selections of time periods between 5 and 80 seconds.

23. The measuring device as recited in claim 16, wherein the stimulator is devised to deliver a physical stimulus with a randomly selected amplitude within a predetermined amplitude range.

24. The measuring device as recited in claim 23, wherein the stimulator is devised to repeatedly in predetermined time intervals randomly select a new amplitude.

25. The measuring device as recited in claim 16, wherein the stimulator is devised to deliver a physical stimulus with a randomly selected pulse width within a predetermined pulse width range.

26. The measuring device as recited in claim 25, wherein the stimulator is devised to repeatedly in predetermined time intervals randomly select a new pulse width.

27. The measuring device as recited in claim 16, wherein the stimulator is devised to repeatedly in predetermined time intervals randomly select a new increase rate.

28. The measuring device as recited in claim 1, wherein the physical stimulus is achieved by exchanging energy with or inducing thermal energy into the skin of a human being.

29. The measuring device as recited in claim 28, wherein the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a sinus wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

30. The measuring device as recited in claim 28, wherein the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined

initial temperature and a predetermined maximum or minimum temperature.

31. The measuring device as recited in claim 28, wherein the stimulator is capable of delivering a pulsating thermal energy exchange or induction stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds.

32. The measuring device as recited in claim 28, wherein the physical stimulus is achieved by means of delivering heat or radiation energy to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades.

33. The measuring device as recited in claim 32, wherein the stimulator is devised to vary the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in the range of 10 to 60 seconds.

34. The measuring device as recited in claim 28, wherein the physical stimulus is achieved by means of cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades.

35. The measuring device as recited in claim 34, wherein the stimulator is devised to vary the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

36. The measuring device as recited in claim 28, comprising a resistive coil or a peltier element.

37. The measuring device as recited in claim 28, comprising a laser, such as an argon laser or a carbon dioxide laser.

38. A sensation level measuring device comprising:
a stimulator devised to selectively deliver a first physical stimulus that is comparable with an affective component of said sensation or a second physical stimulus that is comparable with a sensory component of said sensation.

39. The measuring device as recited in claim 38, further comprising the features of claims

40. An apparatus for measuring the level of a sensation, perception or integrated skill of a person, the apparatus being provided with:
-a stimulus signal generator (102) coupled to stimulus induction means (104) for inducing a pulsating physical stimulus to said person;
-an indication mechanism (124), that is actuateable by said person, for indicating that a stimulus is experienced by the person to correspond to the level of said sensation;
-a level registration means (114,116) for registering a sensation level value corresponding to said sensation,
characterized in means (122) for modulating the pulse width of the physical stimulus with a constant frequency and a constant amplitude for the purpose of measuring the level of an affective component of said sensation.

41. The apparatus of claim 40, further comprising means (120) for modulating the amplitude of said pulsating stimulus with a constant frequency and a constant pulse width for the purpose of measuring the level of a sensory component of said sensation.

42. The apparatus of claim 40, wherein the stimulus signal generating means (102) further comprises a direct current generator or a constant voltage generator capable of delivering an electrical current through a resistance of 0-20 kohm via stimulus induction means (104) in the shape of electrodes applicable against the skin of said person.

43. The apparatus of claim 40, wherein the pulsating stimulus providing means (106) further comprises an oscillator (108) being devised to provide a stimulus signal in the form of a sinus wave having a frequency in the range of 1-100 Hz.

44. The apparatus of claim 40, wherein the pulsating stimulus providing means (106) further comprises a square and/or triangular wave generator (110) being devised to provide a stimulus signal in the form of a square wave having a frequency in the range of 1-100 Hz.

45. The apparatus of claim 43 or 44, further being capable of varying the amplitude of an electrical current stimulus signal in the range of 0-100 mA, preferably increasing with incremental steps in the range f 0.5 mA and preferably having a fixed pulse width in the range of 50-1000 microseconds.

46. The apparatus of claim 43 or 44, further being capable of varying the pulse width of an

electrical current stimulus signal in the range of 0-1000 microsecond, preferably increasing with incremental steps in the range of 5-10 microseconds and preferably having a fixed amplitude in the range of 5-20 mA.

47. The apparatus of claim 43 or 44, further being devised to increase the pulse width of an electrical stimulus signal at a first increase rate in a first pulse width range, preferably such that the pulse width increases from 0-250 microseconds within a time period between 15 and 40 seconds, and at a second increase rate in a second pulse width range preferably such that the pulse width increases from 251-500 microseconds in 20 seconds.

48. The apparatus of claim 43 or 44, further being devised to increase the amplitude of an electrical current stimulus signal at an increase rate in an amplitude range, preferably such that the amplitude increases from 0-100 mA within a time period between 5 and 80 seconds.

49. The apparatus of claim 47 or 48, further being devised to change said time period between every two tests, when using the same increase range for one and the same person.

50. The apparatus of claim 43 or 44, further being devised to generate an electrical current stimulus signal with a randomly selected first amplitude, to maintain said selected amplitude for a period of time and to thereafter randomly select a second amplitude higher than the first amplitude.

51. The apparatus of claim 43 or 44, further being devised to generate an electrical current stimulus signal with a randomly selected first pulse width, to maintain said selected pulse width for a period of time and new higher or pulse width values within predetermined levels, to maintain said selected values for a period of time, and to thereafter randomly select a second pulse width wider than the first pulse width.

52. The apparatus of claim 40, further being devised to increase the stimulation signal starting at a signal level dependent on a previously stored perception threshold.

53. The apparatus of claim 40, further being devised to increase the stimulation signal up to a signal level dependent on a previously stored sensation or tolerance threshold.

54. The apparatus according to any of the claims 40-53, wherein the stimulus induction means (104) comprises a thermal element for emitting a stimulus in the form of thermal

energy.

55. The apparatus of claim 54, wherein the thermal element is a resistive coil or a peltier element.

56. The apparatus of claim 54, wherein the thermal element is a laser, such as an argon laser or carbon dioxide laser.

57. The apparatus of claim 54, further being devised to provide a heat stimulus having an amplitude increasing from an initial temperature preferably in a range of 34 centigrades to a maximum temperature preferably in the range of 60 centigrades, preferably increasing with incremental steps in the range of 0.1 centigrades.

58. The apparatus of claim 57, further being devised to vary the increase rate such that the heat stimulus increases from said initial temperature to said maximum temperature during a time period in the range of 10-60 seconds.

59. Use of an apparatus as recited in any of the claims 1-58 in measuring the level of a sensation.

60. Use of an apparatus as recited in any of the claims 1-58 in measuring the level of a perception.

61. Use of an apparatus as recited in any of the claims 1-58 in measuring the level of an integrated skill.

62. A method of measuring the level of a sensation, perception or integrated skill of a person, comprising the steps of:
delivering to said person a physical stimulus that is comparable with an affective component of said sensation;
registering a first sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation.

63. The method as recited in claim 62, further comprising the step of delivering a pulse width modulated pulsating physical stimulus.

64. The method as recited in claim 62, further comprising the step of delivering a pulsating physical stimulus with a varying pulse width, a fixed frequency and a fixed amplitude.

65. The method as recited in claim 62, further comprising the step of delivering a physical stimulus that is co[redacted]able with a sensory component of sa[redacted]nsation.

66. The method as recited in claim 62, further comprising the step of delivering an amplitude modulated pulsating physical stimulus.

67. The method as recited in claim 62, further comprising the step of achieving the physical stimulus by delivering electrical energy to the skin of a human being.

68. The method as recited in claim 67, wherein said electrical energy is voltage controlled.

69. The method as recited in claim 67, wherein said electrical energy is current controlled.

70. The method as recited in claim 67, further comprising the step of delivering electrical energy in the shape of a voltage or a current through a resistance of 0-20 kohm.

71. The method as recited in claim 67, further comprising the step of delivering electrical energy in the shape of a voltage or a current in a sinus wave, preferably having a frequency in the range of 1-100 Hz.

72. The method as recited in claim 67, further comprising the step of delivering a electrical energy in the shape of a voltage or a current in a square wave and/or a triangular wave, preferably having a frequency in the range of 1-100 Hz.

73. The method as recited in claim 67, further comprising the step of varying the amplitude of a pulsating electrical current in the range of 0-100 mA.

74. The method as recited in claim 67, further comprising the step of varying the amplitude of a pulsating electrical current with steps in the range of 0,5 mA.

75. The method as recited in claim 67, further comprising the step of varying the pulse width of a pulsating electrical energy wave in the range of 0-1000 microseconds.

76. The method as recited in claim 67, further comprising the step of varying the pulse width of a pulsating electrical energy wave with steps in the range of 5-10 microseconds.

77. The method as recited in claim 62, further comprising the step of delivering a pulsating physical stimulus with a variable increase rate.

78. The method as recited in claim 77, further comprising the step of delivering said physical stimulus at a first increase rate in a first measurement and at a second increase rate in a subsequent second measurement.

79. The method as recited in claim 77, further comprising the step of delivering said physical stimulus at a first increase rate within a first pulse width range in a first measurement and at a second increase rate within a second pulse width range in a subsequent second measurement.

80. The method as recited in claim 77, further comprising the step of increasing said physical stimulus within a selected time period in a predetermined range of time and said selected time period is different between every two measurements on the same measurement object.

81. The method as recited in claim 79, further comprising the step of increasing the pulse width from about 0 to about 250 microseconds within a first time period between 15 and 40 seconds in said first increase rate, and from about 251 to about 500 microseconds within a second time period between 15 and 40 seconds selected to be different from said first time period.

82. The method as recited in claim 77, further comprising the step of delivering said physical stimulus at a first increase rate within a first amplitude range in a first measurement and at a second increase rate within a second amplitude range in a subsequent second measurement.

83. The method as recited in claim 82, wherein said first and second amplitude ranges are different selections from the range of 0-100 mA, and said first and second increase rates are based on different selections of time periods between 5 and 80 seconds.

84. The method as recited in claim 77, further comprising the step of delivering a physical stimulus with a randomly selected amplitude within a predetermined amplitude range.

85. The method as recited in claim 84, further comprising the step of repeatedly in predetermined time intervals randomly selecting a new amplitude.

86. The method as recited in claim 77, further comprising the step of delivering a physical stimulus with a randomly selected pulse width within a predetermined pulse width range.

87. The method as recited in claim 86, further comprising the step of repeatedly in predetermined time intervals randomly selecting a new pulse width.

88. The method as recited in claim 77, further comprising the step of repeatedly in predetermined time intervals randomly selecting a new increase rate.

89. The method as recited in claim 62, further comprising the step of achieving the physical stimulus by exchanging thermal energy with or inducing thermal energy into the skin of a human being.

90. The method as recited in claim 89, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a sinus wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

91. The method as recited in claim 89, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

92. The method as recited in claim 89, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds.

93. The method as recited in claim 89, further comprising the step of achieving the physical stimulus by delivering heat to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades.

94. The method as recited in claim 93, further comprising the step of varying the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in the range of 10 to 60 seconds.

95. The method as recited in claim 89, further comprising the step of achieving the physical stimulus by cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades.

96. The method as recited in claim 95, further comprising the step of varying the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

97. A method for measuring the level of a sensation, perception or integrated skill of a person, comprising the steps of:
selectively delivering to said person a first physical stimulus that is comparable with an affective component of said sensation or a second physical stimulus that is comparable with a sensory component of said sensation;
registering a sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation;
indicating whether the registered sensation level value is based on said first physical stimulus or said second physical stimulus respectively.

98. The method as recited in claim 97, further comprising the steps of claims 63-96.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
P11181-M/MIK		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 00/ 08207	21/08/2000	20/08/1999
Applicant		
CEFAR PAINMATCHER AB		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
EP 00/08207

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/103

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 191 896 A (E. GAFNI ET AL.) 9 March 1993 (1993-03-09)	1-3, 16-19, 23,24,28
X	column 1, line 38 -column 2, line 18	30,34,36
X	column 2, line 40 -column 3, line 30	38-40, 52-55,59
X	column 3, line 51 -column 4, line 68	60,62-64
X	column 5, line 22 -column 6, line 20	77-80, 84-89, 91,93, 95,97

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
12 December 2000	18/12/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Rieb, K.D.

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]EP 00/08207

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 06730 A (J. KATIMS) 27 February 1997 (1997-02-27)	1,4-6, 11,16-19
X	page 7, line 23 -page 8, line 16	23-27,38
X	page 10, line 12 -page 15, line 7	41,44, 49-53
X	page 22, line 21 -page 23, line 23	59,60,62
X	page 25, line 2 -page 26, line 10	65-67, 77-80
X	page 28, line 9 -page 31, line 8	84-86,97

X	DE 92 04 961 U (H. MÜLLER ET AL.) 17 June 1992 (1992-06-17)	1,3-8, 10,11
X	page 3, line 2 -page 4, line 14	16-18,28
X	page 4, line 22 -page 5, line 32	32,34,38
X	page 8, line 1 - line 13	41,59, 60, 65-69, 89,95,97

X	EP 0 242 814 A (MAX-PLANCK-GESELLSCHAFT) 28 October 1987 (1987-10-28)	1,4,5, 16,24
X	column 1, line 31 -column 2, line 39	32,34, 36,38,41
X	column 3, line 15 - line 52	50,52-55
X	column 4, line 50 -column 5, line 30	59,60, 62,63, 77,84, 89,91, 95,97

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
[redacted]EP 00/08207

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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WO 9706730	A	27-02-1997	US	5806522 A	15-09-1998
			AU	6726196 A	12-03-1997
			CA	2229656 A	27-02-1997
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			JP	9117453 A	06-05-1997
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EP 242814	A	28-10-1987	US	4763666 A	16-08-1988
			DE	3782082 A	12-11-1992
			DE	3782082 T	06-05-1993

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— *With international search report.*
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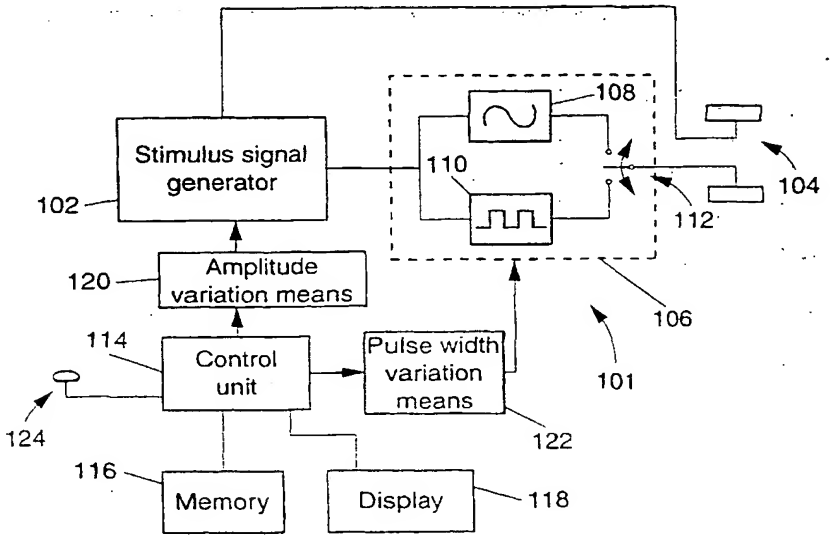
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** APPARATUS FOR PROVIDING AN INDICATION OF SELECTED COMPONENTS OF A SENSATION



(57) **Abstract:** An apparatus for measuring the level of a sensation, perception or integrated skill of a person, the apparatus being provided with stimulating means for inducing a physical stimulus to the person and means for registering a sensation level value in response to an indication signal from the person that the induced stimulus corresponds to the sensation to be measured. The apparatus is devised to provide a pulsating stimulus having means for varying the pulsating properties of the stimulus with pulse width modulation in order to measure the affective component of sensations. Further developments of the apparatus is also provided

SIFICATION OF SUBJECT MATTER
A61B5/103

g to International Patent Classification (IPC) or to both national classification and IPC

DS SEARCHED

documentation searched (classification system followed by classification symbols)
A61B

ntation searched other than minimum documentation to the extent that such documents are included in the fields searched

ic data base consulted during the international search (name of data base and, where practical, search terms used)

Internal

UMENTS CONSIDERED TO BE RELEVANT

y °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 5 191 896 A (E. GAFNI ET AL.) 9 March 1993 (1993-03-09) column 1, line 38 -column 2, line 18 column 2, line 40 -column 3, line 30 column 3, line 51 -column 4, line 68 column 5, line 22 -column 6, line 20 --- -/--	1-3, 16-19, 23,24,28 30,34,36 38-40, 52-55,59 60,62-64 77-80, 84-89, 91,93, 95,97

Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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of the actual completion of the international search	Date of mailing of the international search report
12 December 2000	18/12/2000
e and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040 Tx. 31 651 epo nl	Authorized officer

Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
WO 97 06730 A (J. KATIMS) 27 February 1997 (1997-02-27) page 7, line 23 -page 8, line 16 page 10, line 12 -page 15, line 7 page 22, line 21 -page 23, line 23 page 25, line 2 -page 26, line 10 page 28, line 9 -page 31, line 8	1,4-6, 11,16-19 23-27,38 41,44, 49-53 59,60,62 65-67, 77-80 84-86,97
DE 92 04 961 U (H. MÜLLER ET AL.) 17 June 1992 (1992-06-17) page 3, line 2 -page 4, line 14 page 4, line 22 -page 5, line 32 page 8, line 1 - line 13	1,3-8, 10,11 16-18,28 32,34,38 41,59, 60, 65-69; 89,95,97
EP 0 242 814 A (MAX-PLANCK-GESELLSCHAFT) 28 October 1987 (1987-10-28) column 1, line 31 -column 2, line 39 column 3, line 15 - line 52 column 4, line 50 -column 5, line 30	1,4,5, 16,24 32,34, 36,38,41 50,52-55 59,60, 62,63, 77,84, 89,91, 95,97

APPARATUS FOR PROVIDING AN INDICATION OF SELECTED COMPONENTS OF A SENSATION

Technical Field

The present invention relates generally to an apparatus for assessing the level of comfort or discomfort in a positive or negative sensation experienced by a person. More particularly, the invention relates to an electronic apparatus being devised to provide a variable stimulus to the person until the applied stimulus matches the experienced sensation.

Background

In medical as well as psychological treatment there is a need to quantify the sensation experienced by the patient, for example in order to select an appropriate treatment and to determine the need of drugs or the effect of a pursued treatment. This is based in the individual need for an adequate treatment as well as for conveying an understanding of the personal situation for example to a doctor. There is also a social need to control the overall consumption of drugs and the general well-being of the population. In order to meet these and other needs, an efficient tool for quantifying sensations, particularly those related to medical or psychological disorders, is required.

The best known field for quantifying sensations is perhaps the assessment of pain, and prior art within this field has evolved from general statements of the status in response to questions from a doctor to simple aids such as the widely used sliding scale for quantifying a sensation of pain. Commonly used such scales are for example the visual analogue scale (VAS) and other ordered category scales, i.e. numeric rating scales (NRS). A disadvantage with these methods is the unreliability inter alia due to a relative scale which is strongly dependent on unconscious or conscious subjective influence by the patient. Other limitations in the scale based methods are the fixed end points of the scale entailing a limited range of measurement and the fact that comparisons can only be made between different measurements on the same individual, not between different individuals.

In order to produce a more reliable result an electronic instrument and a method for measuring an arbitrary feeling e.g. pain or nausea has been suggested and presented in the patent publication WO 97/24068 (Laserow), which is herewith incorporated by reference. This instrument is devised to apply a physical stimulus to the patient, e.g. in the form of an electrical current, and the stimulus is increased until the patient experiences a discomfort that is comparable to the pain or nausea that is to be quantified. The patient then actively or passively ceases the induced stimulus and a value is registered. It has been found that this way of quantifying pain or other discomfort is repeatable and more reliable than previous methods. Furthermore, the measurement is unbiased since the patient is not aware of the resulting value but only of the stimulus to be compared to the feeling to be assessed.

Another prior art method directed to the quantification of the emotional state following a dysphoric condition, such as depression, anxiety or pain; is disclosed in US Patent No. 4,844,091 to Bellak. This piece of prior art describes a method wherein an increasing acoustical stimulation is applied to a patient until the level of the acoustical stimulation is associated with the level of the dysphoric condition.

It is well known that many sensations have a sensory component as well as an affective component. The sensory component typically corresponds to the intensity of the sensation, where it is located, duration and so on, whereas the affective component rather corresponds to the discomfort and the aspects that affect the quality of life. This is probably due to the fact that a sensation, e.g. pain, is on one hand registered in the cerebral cortex which is responsible for the experience of intensity, localisation and duration. On the other hand the sensation is also registered in nuclei that affect the emotional life, i.e. in the limbic system. This fact entails difficulties in determining the appropriate measures to be taken against for example a dysphoric condition. So may, for example, a much lesser amount of analgesics actually be needed in order to eliminate pain than the measurement value according to prior art method suggests. In other situations, e.g. where a mainly emotional sensation should be assessed there is in prior art an uncertainty as to what component is actually measured.

Accordingly, there is a need for an improved apparatus that gives a reliable and repeatable indication of the different components of the experienced sensation.

From a practical point of view the evaluation of symptoms and different functional disorders of patients is a frequently occurring task in the normal clinical work. The evaluations are registered in order for the purpose of establishing optimal opinions of the state of health, of deciding on a treatment or to follow up the result of a treatment. Furthermore, the clinical evaluation methods have to be fast and simple to perform in order to fit into the stressful working conditions of today. The instruments that are used in the evaluation should also be tested to give reliable results, i.e. to give the same results in repeated measurements and to measure the intended parameters. Naturally, the instruments also must be safe to use without any risk of hurting the patient.

Accordingly, there is furthermore a need for an improved apparatus that ensures a reliable assessment of the sensations to be measured also under disturbing circumstances and despite possible attempts from the patient to manipulate the measurement.

Objects of the Invention

It is therefore an object of the present invention to solve the problem of providing an improved apparatus that enables separate measuring of the affective component of a sensation.

An aspect of the problem to be solved is to distinguish between the sensory and the affective components of sensations. More particularly, this aspect of the problem concerns

how to measure the sensory and the affective components, respectively.

Another aspect of the problem is to provide a suitable type of stimulation.

Yet another aspect of the problem to be solved is to ensure the reliability of a measurement and to render the detection of an erroneous measurement possible.

Summary of the Invention

The present invention is based on the realisation of the inventors that the result of the measurement is dependent on the type of the applied stimulus. The basic principle of the invention is to let a person compare an induced physical stimulus with a current or a previously experienced sensation, perception or integrated skill by making an analogy between the sensation caused by the induced stimulus and the sensation to be measured. This is also known as sensation matching, e.g. pain matching.

The inventors have found that sensations to be measured are best compared with a pulsating stimulus in order to achieve a reliable result. In parts of a measurement or for measuring specific sensations or components of sensations, a constant stimulus, which can be regarded as a pulsating stimulus having an infinite pulse width, may be used. Stimuli according to different embodiments of this invention are for example energy forms such as electricity, cold and heat. Electrical stimulation is perhaps the most reliable energy form for the stimulus since it is easy to control and it gives constant measurement values, which in its turn generates measurement results that are comparable between different individuals. However, other energy forms may be more suitable in specific conditions or situations.

The sensory component of a sensation has been found to be best compared with a stimulus in the shape of a pulsating energy wave where the amplitude is varied, in most cases increased, in order to determine a level of this component. The sensory component typically reflects the intensity or strength of a compound sensation having both components.

Furthermore, it has been found that specific stimuli are comparable with affective components of sensations and are according to the invention applied in order to discriminate the affective component from the sensory component of the sensation. In accordance with an embodiment of the invention, the affective component of a sensation is advantageously compared with a stimulus in the shape of a pulsating energy wave where the pulse width is varied, in most cases increased, in order to determine the relevant level of the affective component. A particularly advantageous embodiment of such a pulse width modulated pulsating stimulus is applied with a constant amplitude and a constant frequency. In a series of measurements the pulse width modulation may be employed with different levels of amplitudes and frequencies that are fixed within each measurement. The affective component typically reflects the level of comfort or discomfort in a compound sensation having both components. When measuring a sensation known to have none or

only a negligible amount of one of the components, it may be sufficient to apply the stimulus suitable for the mainly occurring component. However, it is often an advantage to cross match the measurement results for different components.

Physiological reasons for the suitability of the mentioned stimulus variation schemes for the affective component and the sensory component, respectively, are explained below. In addition, experimental test series on human test groups strongly support this functional relationship.

Different sensations may, according to an embodiment of the invention, also be measured by applying different frequencies for different sensations. There are physiological as well as a psychological reasons for this, i.e. physical stimuli having certain varying properties or parameters, e.g. in terms of amplitude, pulse width, frequency settings or increase rate, are suitable for comparing certain sensations. When conducting measurements on different types of sensations it is also psychologically appropriate to vary the type of stimulation in order to separate the sensations in the mind of the measured person. In one embodiment of the invention, the apparatus is devised to selectively, in a predetermined or random scheme, alternately deliver a first physical stimulus that is comparable with an affective component of the sensation and a second physical stimulus that is comparable with a sensory component of the sensation. The parameter values are registered and assorted according to the measured component , and then presented to the user for evaluation.

According to an aspect of the invention, the reliability of a measurement is checked by conducting a series of measurements with different variations in the stimulation. In a preferred embodiment of the invention this variation is achieved by varying the increase rate of the physical stimulus, e.g. varying the increase rate of the pulse width or the pulse amplitude. So, if for example a test object indicates a sensation match after the same period of time in two different stimulation sequences of the same measurement session, different measurement results in terms of parameter values will be obtained. Thereby it is possible to detect erroneous measurement conditions or an unconscious or conscious attempt to manipulate the measurement. If on the other hand the test object indicates a match at the same or in a close range of parameter values in subsequent stimulation sequences with different increase rates, it is a strong indication that the measurement is correct and reliable. In a basic variety of this inventive feature, the apparatus is devised to deliver the physical stimulus at a first increase rate in a first measurement and at a second increase rate in a subsequent second measurement. Further features are of this embodiment are explained below.

The reliability of the measurement is in another embodiment of the invention checked by first detecting and storing the perception threshold of the person, by gradually increasing the stimulation until the person signals a perceived stimulation. In a similar manner the sensation threshold of the person is detected, i.e. the threshold at which the

patient begins to experience a similar or an analogue sensation. This threshold is perhaps mostly used in connection with pain measurement where it is consequently called pain threshold, i.e. the point at which the patient begins to experience pain. Again in a similar manner, the tolerance threshold of the person is detected and stored when the person signals an unbearable stimulation. The inventors have found that the most relevant measurement results are obtained in the range between the perception threshold and the tolerance threshold, evidently because below and above these threshold the patient is generally not able to distinguish between different stimulation levels. In a subsequent measurement session the scales of the measurement values may then be adjusted dependent on the stored individual threshold values. For checking purposes, it is utilised in embodiments the invention the fact that it is unlikely that someone would estimate a sensation as corresponding to a stimulus below the perception threshold. In ordinary measuring, valuable measuring time is saved by starting the stimulation close to the perception threshold. Furthermore, it is preferable to adjust the scale running from absence of sensation to unbearable sensation such that it starts on the perception threshold. For safety reasons it is also preferable to set a maximum stimulus below the tolerance threshold in order to minimise the risk of hurting the patient.

Experimental studies on patients with chronic nociceptive or neurogenic pain have shown that the apparatus according to the invention presents a less systematic disagreement and a greater augmented rank order coefficient than the above mentioned VAS and NRS. Advantages that are obvious from the studies are that the inventive apparatus is simple and safe to use, and that it seems to give more objective values for further analyses. Furthermore, neither any possible expectation of the test leader nor of the patient influences the direct outcome of the measurements.

Brief Description of the Drawings

The invention will now be further described in conjunction with the drawings, wherein Fig 1 and Fig 2 show block diagrams of the functional components of the inventive apparatus.

Detailed Description of Embodiments

The invention facilitates the measurement of a senso-neuropsychological quantity in a person by inducing sensation levels, e.g. energy levels or pain levels, as a reference. The person in his or her turn is instructed to compare the induced level with the level to be measured, which for example can be a level of an actual pain, a remembered pain or a level of another sensation, perception or integrated skill relating to sensory modalities such as sight, smell, hearing, touch or taste. The level to be measured can also be a level of a feeling or of an ability. The person is further instructed to indicate which induced sensation level that best coincides with the level of the senso-neuropsychological quantity that is

measured. In compound sensations both the sensory as well as the affective component can be measured by means of the invention. When it comes to abilities, diability or an integrated skill which requires an observer of the patient to assess the level, the stimulus is subjected to the observer who matches the induced stimulus with his or hers perception of the level of the patient's senso-neuropsychological quantity.

The term senso-neuropsychological quantity is in this text used as a common expression for the complex of sensations, perceptions and integrated skills and disabilities. However, for the sake of simplicity also the simpler term sensation will be used as a synonym. Such quantities or sensations for example include pain, nausea, tinnitus, tiredness, muscle weakness, spasticity, vomiting need, anxiety, fear, state of being, abstinence, itch, luxation, heartbeat, cramp, suffocation, allergy, sleep, sensitivity, motoric phenomena or motoric problems, ache, apathy, ataxia, aphasia, athetosis, degree of infection, fever, numbness, swelling, intoxication, inflammation, burning, cognitive or mnemonic ability, joy, comfort, vision, paresthesia, dysphagia, sweating reflexes, movement, quality of life and ADL (active daily living skills).

In a first embodiment of the invention the physical stimulation is achieved by delivering an electrical energy wave, preferably electrical pulses to the nerves in the skin of a person. Nerve fibres in a resting state have a potential difference of 70mV across the fibre membrane, the inside being negative and the outside positive. When a nerve is stimulated an action potential arises from sequential changes in the selective permeability of the membrane to sodium (Na+) and potassium (K+) ions through channels. These voltage-gated ion channels are critical for generating action potentials. The nervous system expresses a rich variety of types of voltage-gated ion channels and each type has itself many variants. The channels differ in their kinetics of activation, voltage activation range and sensitivity. Also the opening and closing of certain voltage-gated ion channels can be modulated by various cytoplamic factors, resulting in increased flexibility of the neuron's excitability properties. In general the amplitude of current needed to stimulate a nerve is inversely proportional to its diameter. Thus the small C-fibres carrying the dull and aching pain associated with unpleasantness need the highest current or voltage amplitude and the longest pulse width whereas the small A-delta fibres carrying the sharp and intense pain requires a shorter pulse width to be stimulated. Furthermore, the impedance of the skin is dependent on pulse width, the impedance being much less for shorter pulses.

In the present invention, the inventors have utilized these basic physiological differences and constructed a sensation matching unit enabling assessment of sensation intensity, e.g. pain intensity, with an amplitude modulated stimulation signal using short pulses with fixed pulse width and increasing pulse amplitude thereby stimulating mainly A-delta fibres. This stimulation mode is in the invention used to measure the sensory component of sensations.

Furthermore, the affective component of a sensation such as discomfort associated with pain or unpleasantness is in accordance with the invention measured with a pulse width modulated stimulation signal using fixed pulse amplitude and an increasing pulse width thereby stimulating mainly C-fibres.

The invention is mainly intended to be applied in a portable measurement device such as the one disclosed in the above mentioned prior art document WO 97/24068 (Laserow), however other stationary or semi-stationary apparatuses are also conceivable within the inventive concept.

Fig 1 shows a block diagram of the functional structure of embodiments of the invention. The functional structure comprises a stimulus signal generator 102 coupled via means 106 for providing a pulsating stimulus to stimulus induction means 104, which in use are intended to be applied to the skin of a person for inducing a stimulus. A control unit 114, for example a control processor, is coupled to the stimulus signal generator 102 via an amplitude variation means 120 devised for varying the amplitude of the pulsating stimulus signal and thereby also varying the output stimulus in order to measure the level of a sensory component of a sensation. The control unit is also coupled to the pulsating stimulus providing means 106 via a pulse width variation means 122 devised for varying the pulse width of the pulsating stimulus signal in order to measure the level of an affective component of a sensation. The control unit is further coupled to a memory 116 for storing registered measurement values and control instructions for predetermined control schemes, and a display 118 for the visual presentation of an obtained measurement value or other information. The control unit is also optionally coupled to a control switch 124, e.g. a button, for starting, stopping or halting a measurement sequence at for example a perception threshold, sensation threshold, tolerance threshold or sensation level. In a preferred embodiment, the apparatus is devised to stop a variation of the pulsating properties of the stimulus in response to an actuation of the control switch 124, and the apparatus is devised to keep the pulsating property at its current level. So, for example, may the patient stop an increase in amplitude or pulse width at a level which seems to match the measured sensation and consider whether the level is correct. If the patient indeed considers the level to be correct, the patient releases his or her contact with the induction means 104. This leaves an open circuit which is detected by the apparatus, whereupon it is devised to automatically store the current value of amplitude and/or pulse width. A separate electrical circuit may be provided for the detection of an open circuit due to the patient's release of the contact with the induction means. If the halted level is not considered to be corrected, the patient may continue the increase, or variation, by releasing the button, resuming the contact or switch back to an initial switch position.

In the embodiment as shown in Fig 1, the means 106 for providing a pulsating stimulus further comprises means 108 for providing a pulsed current stimulus intensity, e.g. in the shape of an oscillator, and/or means 110 for providing a square waved stimulus

intensity, e.g. in the shape of a square wave or a triangle wave generator, either of the means 108 and 110 being devised to provide a stimulus signal in the form of a pulsed current having a frequency in the range of 1-100 Hz. In Fig 1 is also shown a switching means, controllable by the control unit and being devised to switch between the different wave forms.

In Fig 2, a more specific embodiment devised for delivering stimuli in the shape of a pulsated electrical current is shown. One of two electrodes 204 is coupled to a switched power supply 216 which in its turn is coupled or couplable to an energy source 218, e.g. a battery. The second electrode 204 is coupled to a constant current generator (CCG) 202 for generating a stimulus signal. The switched power supply 216 and the constant current generator 202 are coupled to a microprocessor 206 provided with an in/out (I/O) interface 212 such as a key board and/or a display. The pulses are generated by means of the microprocessor and conveyed to the electrode 204 from the constant current generator 202 via a digital to analog converter (D/A) 210 coupled intermediate the microprocessor 206 and the constant current generator 202. In this embodiment the amplitude variation means, the pulse width variation means and means for achieving a selected pulse shape are realised by a specific program run on the microprocessor. Different curve forms and increase rates are in a similar manner also achieved by the microprocessor.

An analog to digital (A/D) converter 208 is further coupled between the constant current generator 202 and the microprocessor 206 in order to facilitate a feedback for detection of closed or open circuit between the electrodes. This detection is provided in order to control the start of a measurement sequence when the electrodes are gripped by a person and/or the registration of a measurement value when the electrodes are released by said person and the circuit is broken.

In a first embodiment devised for applying an electrical current stimulus, the stimulus signal generator comprises a constant current generator or a constant voltage capable of delivering an electrical current through a resistance preferably in the range of 0-20 kohm. The apparatus can be either current controlled or voltage controlled and the parameter scales adjusted in accordance with the realised control type. The electrodes of preferred embodiments of the apparatus are intended to be applied to the skin of the persons to be measured. The electrodes are thereby preferably devised to contact the skin between the fingers in a tweezers grip and are therefore provided with a metal surface or a conductive silicone rubber surface.

This apparatus would further be capable to vary the amplitude of an electrical current stimulus signal in the range of 0-100 mA, preferably increasing with incremental steps in the range of 0.5 mA and preferably having a fixed pulse width in the range of 50-1000 microseconds. The apparatus would also or instead further be capable to vary the pulse width of an electrical stimulus signal in the range of 0-1000 microsecond, preferably increasing with incremental steps in the range of 5-10 microseconds and preferably having

a fixed amplitude in the range of 5-20 mA. In one embodiment or application of the invention the pulsating physical stimulus or the stimulus signal is pulse width modulated by varying the pulse width but maintaining for a predetermined period of time a fixed amplitude and/or a fixed frequency. It is clear that this feature cannot be achieved with a sinus wave, it is rather required an unsymmetrical pulse wave in the sense that pulse and base level can have a different duration.

In either forms of stimulus, amplitude modulated or pulse width modulated, the pulse wave may be biased or superposed on a constant current in order to overcome a basic skin resistance. The skin resistance may be different for different persons, for example due to different bodily constitution or personal skin properties. Preferably, adjustments in the stimulation scheme due to such personal properties are stored for example in a digital storage device or in the shape of parameter values that can be input into or adjusted on measurement devices in accordance with the invention. Thereby ensuring reliability and repeatability of measurements on a specific person.

In order to increase the reliability of the measurement apparatus as discussed above, one embodiment is devised to increase the pulse width of the electrical current stimulus signal at a first increase rate in a first pulse width range. This is, in a preferred embodiment employed such that the pulse width increases from 0-250 microseconds within a first time period between 15 and 40 seconds, and at a second increase rate in a second pulse width range preferably such that the pulse width increases from 251-500 microseconds within a second time period between 15 and 40 seconds, e.g. in 20 seconds. The apparatus is further devised to increase the amplitude of an electrical current stimulus signal at a first increase rate within a first amplitude range and at a second increase rate within a second amplitude range. The first and second amplitude ranges are different selections of combinations of amplitude ranges from the range of 0-100 mA and time periods between 5 and 80 seconds. For example, the increase rate may be such that the amplitude increases from 0-100 mA within a certain time period, which time period may last between 5 and 80 seconds

The purpose of using different time periods for the increase of pulse width or amplitude within a specific range, and thus the increase rate, is to make the measurement independent of the subjected person's perception of time. With varying increase rates from one test to another, the person subjected to the test is not led to make his or her indication based on the memory of the previous test, regarding the time elapsed since the beginning of the stimulus induction. The person therefore needs to focus only on the induced stimulus, which in turn results in a more reliable measurement. For this reason, embodiments of the inventive apparatus is devised to never use the same time period, for a certain increase range and a certain person, twice in a row. The stimulator may for example be devised to repeatedly in predetermined time intervals randomly select a new increase rate. For example, the apparatus may be devised to change said time period randomly, although with a time period of at least 5 seconds, between every two tests.

In order to adjust the scales of the measurement result, one embodiment of the invention is devised to increase the stimulation signal starting at a signal level dependent on a previously stored perception threshold. This perception threshold is preferably found in a dedicated measurement cycle. Likewise is another embodiment devised to increase the stimulation signal up to a signal level dependent on a previously stored sensation or tolerance threshold.

In addition to the operation with increasing current and/or heat amplitude, as well as increasing pulse width, the inventive apparatus is capable of running according to a randomized stimulation scheme. In such a scheme, the induced stimuli has a random value both with regard to amplitude and, for electrical current, pulse width. Preferably, higher values close to the tolerance threshold are avoided in the randomized stimulation scheme. A certain random value, or set of values, is maintained for a specific time period, long enough for a person to be able to indicate that the stimuli matches the sensation to be measured. After said time period, the induced stimuli assumes a new random value, or set of values. Thus, in varieties of the invention, the stimulator is devised to deliver a physical stimulus with a randomly selected amplitude within a predetermined amplitude range, and to repeatedly in predetermined time intervals randomly select a new amplitude. Still a further variety is devised to deliver a physical stimulus with a randomly selected pulse width within a predetermined pulse width range, and to repeatedly in predetermined time intervals randomly select a new pulse width.

In one variety of the inventive apparatus the stimulus induction means 104 comprises a heat generating devise for emitting a stimulus by exchanging or inducing thermal energy with the skin of the person. The thermal energy exchange may be carried out by delivering heat to the skin of the person or by cooling the skin of the person. Different examples of such heat generating devices are resistive coils, peltier elements and lasers, such as argon lasers or carbon dioxide lasers. In the latter examples, radiation energy is transformed to heat in the skin. When using heat as stimulus, the apparatus would be devised to provide a heat stimulus having an amplitude increasing in a range of 20-60 centigrades, preferably increasing with incremental steps in the range of 0.1 centigrades. The increase rate would typically be varied such that the heat stimulus increases from a start temperature to a maximum temperature during an interval in the range of 10-60 seconds.

In one embodiment, the stimulator is devised to be capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a sinus wave within a predetermined initial temperature and a predetermined maximum or minimum temperature. In another embodiment, the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature. The stimulator is typically capable of

delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds. The thermal energy exchange stimulator may also be designed to deliver an increasing, continuous , i.e. not pulsating, thermal energy stimulation. Dependent on the thermal inertia of the selected stimulation induction means, the pulsating properties of a pulsating stimulation may be more or less accentuated.

Specific embodiments are designed such that the physical stimulus is achieved by means of delivering heat to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades. The stimulator may furthermore be devised to vary the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in the range of 10 to 60 seconds.

In embodiments based on cooling, the physical stimulus is achieved by means of cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades. Typically, the stimulator would then be devised to vary the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

The internal structure of an apparatus for stimulation with thermal exchange is basically the same as the one for electrical stimulation, since the thermal elements or electrodes, whatever heating or cooling method is employed, will preferably be electronically controlled in the same manner as the electrical stimulator.

The physiological basis for measuring by means of thermal exchange stimulation in accordance with the invention is that humans recognize four distinct types of thermal sensations, namely cold, cool, which may be painful, warm and hot, which also may be painful. These thermal sensations result from differences between the external temperature of the air or of objects contacting the body and having the normal skin temperature of about 34C. Thermal receptors modulate their firing or activity as a function of temperature. At constant temperature they have tonic discharges, firing action potentials at a steady rate governed by the actual temperature sensed. Cold and warmth receptors fire action potentials continously at low rates when the skin temperature is set at its normal value of 34C. The steady firing rate does not increase or decrease monotonically if the skin is slowly warmed or cooled. Instead, each class of thermal receptors shows peak firing at a preferred skin temperature. Cold receptors are most active at 25C whereas warmth receptors are most active at 45C. Temperatures below or above these values evoke progressively weaker responses. Warmth receptors are unresponsive to hot temperatures, as stimuli above 50C fail to excite them. At these high temperatures humans perceive heat pain rather than sensations of warmth. The corresponding temperature for cool activation is 5C. The frequency of discharge of cold or warmth fibres is linearly related to the size of

the warming or cooling step.

According to one embodiment of the present invention, the apparatus comprises the described means for induction of stimuli in the form of both an electrical current and heat.

The choice of using heat as stimuli, instead of an electrical current, can be dependent on the sensation to be measured. Test results have shown that pain thresholds were elevated following intrathecal morphine when using an argon laser technique for heat stimuli induction, whereas no pain threshold changes were detected using electrical stimulation. A hypothetical explanation to the different results has been that the morphine has different effects on different nerve fibre populations, of which C-fibres are activated by heat and A-delta fibres are activated by electrical stimulation. Similar results have been found when measuring pain threshold elevation following treatment with acupuncture.

According to the invention, the apparatus can be used not only to indicate sensations, but also integrated skills, impairments and disabilities, e.g. quality of life and active daily living, ADL. When using the apparatus for such a purpose, the measured perception threshold and pain threshold are used as lower and upper values on a scale, or vice versa. The integrated skill is then indicated by selecting the appropriate stimulation level, and the measurement result is referred to said scale. The induced stimuli can be either an electrical current or heat. Furthermore, the measurement, or indication, can be performed either by the person subjected by the stimuli, or by another person, based upon this other person's realisation of the integrated skills of the subjective person.

In an exemplifying prototype used for an experimental study of an aspect of the invention, an electrical current stimulus was provided by means of an electrical current generator capable of delivering a current through a resistance of 13 kohm. The current was pulsated in a pulsating square wave shape having a fixed amplitude of 10 mA and a frequency of 10 Hz. The pulse width was increased from 0 to 500 microseconds in steps of about 8 microseconds. The increase rate of the pulse width was devised such that the pulse width was increased from 0 to 250 microseconds during 25, 30 or 35 second, never repeating the same increase rate twice in a sequence, and from 251 to 500 microseconds during 20 seconds. The results of this experimental study verifies the proper function of the invention.

A preferred procedure for using the inventive apparatus for measuring a sensation, using a stimulus signal with an increasing value, comprises the steps of:

- connecting the induction means 104 to a skin portion of the patient, preferably into a finger grip;
- commencing the stimulus induction by pushing the control switch 124, whereupon an increasing stimulus is generated;
- the patient halting the increase of the stimulus signal when sensing that the induced stimulus matches the sensation to be measured, whereby the stimulus signal is held at a constant level;

- the patient considering if said constant level matches the sensation to be measured;
- if indeed considering the stimulation halted at the constant level to represent a good match, the patient releasing the grip of the induction means, the resulting open circuit ending with the released induction means thereby triggering the apparatus to store the currently generated stimulus level;
- if not considering the stimulus at the constant level to match with the sensation to be measured, the patient pushing the control switch once again, thereby continuing the increase from the halted level, until finding a level that better matches the sensation.

As previously described, the inventive apparatus can also be used for measuring a perception or an integrated skill, and may furthermore use a random variation of the stimulus signal instead of an increasing value. The described procedure is however easily modified to any of those cases, and is not intended to be limited by the specific wording of the included steps.

Claims

1. A sensation level measuring device comprising
a stimulator devised to deliver a physical stimulus that is comparable with an affective component of said sensation.

2. The measuring device as recited in claim 1, wherein said stimulator is devised to deliver a pulse width modulated pulsating physical stimulus.

3. The measuring device as recited in claim 1, wherein said stimulator is devised to deliver a pulsating physical stimulus with a varying pulse width, a fixed frequency and a fixed amplitude.

4. The measuring device as recited in claim 1, wherein said stimulator is devised to deliver a physical stimulus that is comparable with a sensory component of said sensation.

5. The measuring device as recited in claim 1, wherein said stimulator is devised to deliver an amplitude modulated pulsating physical stimulus.

6. The measuring device as recited in claim 1, wherein the physical stimulus is achieved by means of delivering electrical energy to the skin of a human being.

7. The measuring device as recited in claim 6, wherein said electrical energy is voltage controlled.

8. The measuring device as recited in claim 6, wherein said electrical energy is current controlled.

9. The measuring device as recited in claim 6, wherein said stimulator is capable of delivering electrical energy in the shape of a voltage or a current through a resistance of 0-20 kohm.

10. The measuring device as recited in claim 6, wherein said stimulator is capable of delivering electrical energy in the shape of a voltage or a current in a sinus wave, preferably having a frequency in the range of 1-100 Hz.

11. The measuring device as recited in claim 6, wherein said stimulator is capable of delivering electrical energy in the shape of a voltage or a current in a square wave

and/or a triangular wave, preferably having a frequency in the range of 1-100 Hz.

12. The measuring device as recited in claim 6, wherein said stimulator is capable of varying the amplitude of a pulsating electrical current in the range of 0-100 mA.

13. The measuring device as recited in claim 6, wherein said stimulator is capable of varying the amplitude of a pulsating electrical current with steps in the range of 0,5 mA.

14. The measuring device as recited in claim 6, wherein said stimulator is capable of varying the pulse width of a pulsating electrical energy wave in the range of 0-1000 microseconds.

15. The measuring device as recited in claim 6, wherein said stimulator is capable of varying the pulse width of a pulsating electrical energy wave with steps in the range of 5-10 microseconds.

16. The measuring device as recited in claim 1, wherein said stimulator is capable of delivering a pulsating physical stimulus with a variable increase rate.

17. The measuring device as recited in claim 16, wherein said stimulator is devised to deliver said physical stimulus at a first increase rate in a first measurement and at a second increase rate in a subsequent second measurement.

18. The measuring device as recited in claim 16, wherein said stimulator is devised to deliver said physical stimulus at a first increase rate within a first pulse width range in a first measurement and at a second increase rate within a second pulse width range in a subsequent second measurement.

19. The measuring device as recited in claim 16, wherein the increase of said physical stimulus is carried out within a selected time period in a predetermined range of time and said selected time period is different between every two measurements on the same measurement object.

20. The measuring device as recited in claim 18, wherein the pulse width increases from about 0 to about 250 microseconds within a first time period between 15 and 40 seconds in said first increase rate, and from about 251 to about 500 microseconds within a second time period between 15 and 40 seconds selected to be different from said first time period.

21. The measuring device as recited in claim 16, wherein said stimulator is devised to deliver said physical stimulus at a first increase rate within a first amplitude range in a first measurement and at a second increase rate within a second amplitude range in a subsequent second measurement.

22. The measuring device as recited in claim 21, wherein said first and second amplitude ranges are different selections from the range of 0-100 mA, and said first and second increase rates are based on different selections of time periods between 5 and 80 seconds.

23. The measuring device as recited in claim 16, wherein the stimulator is devised to deliver a physical stimulus with a randomly selected amplitude within a predetermined amplitude range.

24. The measuring device as recited in claim 23, wherein the stimulator is devised to repeatedly in predetermined time intervals randomly select a new amplitude.

25. The measuring device as recited in claim 16, wherein the stimulator is devised to deliver a physical stimulus with a randomly selected pulse width within a predetermined pulse width range.

26. The measuring device as recited in claim 25, wherein the stimulator is devised to repeatedly in predetermined time intervals randomly select a new pulse width.

27. The measuring device as recited in claim 16, wherein the stimulator is devised to repeatedly in predetermined time intervals randomly select a new increase rate.

28. The measuring device as recited in claim 1, wherein the physical stimulus is achieved by exchanging energy with or inducing thermal energy into the skin of a human being.

29. The measuring device as recited in claim 28, wherein the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a sinus wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

30. The measuring device as recited in claim 28, wherein the stimulator is capable of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined

initial temperature and a predetermined maximum or minimum temperature.

31. The measuring device as recited in claim 28, wherein the stimulator is capable of delivering a pulsating thermal energy exchange or induction stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds.

32. The measuring device as recited in claim 28, wherein the physical stimulus is achieved by means of delivering heat or radiation energy to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades.

33. The measuring device as recited in claim 32, wherein the stimulator is devised to vary the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in the range of 10 to 60 seconds.

34. The measuring device as recited in claim 28, wherein the physical stimulus is achieved by means of cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades.

35. The measuring device as recited in claim 34, wherein the stimulator is devised to vary the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

36. The measuring device as recited in claim 28, comprising a resistive coil or a peltier element.

37. The measuring device as recited in claim 28, comprising a laser, such as an argon laser or a carbon dioxide laser.

38. A sensation level measuring device comprising:
a stimulator devised to selectively deliver a first physical stimulus that is comparable with an affective component of said sensation or a second physical stimulus that is comparable with a sensory component of said sensation.

39. The measuring device as recited in claim 38, further comprising the features of claims

2-37.

40. An apparatus for measuring the level of a sensation, perception or integrated skill of a person, the apparatus being provided with:
-a stimulus signal generator (102) coupled to stimulus induction means (104) for inducing a pulsating physical stimulus to said person;
-an indication mechanism (124), that is actuateable by said person, for indicating that a stimulus is experienced by the person to correspond to the level of said sensation;
-a level registration means (114,116) for registering a sensation level value corresponding to said sensation,
characterized in means (122) for modulating the pulse width of the physical stimulus with a constant frequency and a constant amplitude for the purpose of measuring the level of an affective component of said sensation.

41. The apparatus of claim 40, further comprising means (120) for modulating the amplitude of said pulsating stimulus with a constant frequency and a constant pulse width for the purpose of measuring the level of a sensory component of said sensation.

42. The apparatus of claim 40, wherein the stimulus signal generating means (102) further comprises a direct current generator or a constant voltage generator capable of delivering an electrical current through a resistance of 0-20 kohm via stimulus induction means (104) in the shape of electrodes applicable against the skin of said person.

43. The apparatus of claim 40, wherein the pulsating stimulus providing means (106) further comprises an oscillator (108) being devised to provide a stimulus signal in the form of a sinus wave having a frequency in the range of 1-100 Hz.

44. The apparatus of claim 40, wherein the pulsating stimulus providing means (106) further comprises a square and/or triangular wave generator (110) being devised to provide a stimulus signal in the form of a square wave having a frequency in the range of 1-100 Hz.

45. The apparatus of claim 43 or 44, further being capable of varying the amplitude of an electrical current stimulus signal in the range of 0-100 mA, preferably increasing with incremental steps in the range f 0.5 mA and preferably having a fixed pulse width in the range of 50-1000 microseconds.

46. The apparatus of claim 43 or 44, further being capable of varying the pulse width of an

electrical current stimulus signal in the range of 0-1000 microsecond, preferably increasing with incremental steps in the range of 5-10 microseconds and preferably having a fixed amplitude in the range of 5-20 mA.

47. The apparatus of claim 43 or 44, further being devised to increase the pulse width of an electrical stimulus signal at a first increase rate in a first pulse width range, preferably such that the pulse width increases from 0-250 microseconds within a time period between 15 and 40 seconds, and at a second increase rate in a second pulse width range preferably such that the pulse width increases from 251-500 microseconds in 20 seconds.

48. The apparatus of claim 43 or 44, further being devised to increase the amplitude of an electrical current stimulus signal at an increase rate in an amplitude range, preferably such that the amplitude increases from 0-100 mA within a time period between 5 and 80 seconds.

49. The apparatus of claim 47 or 48, further being devised to change said time period between every two tests, when using the same increase range for one and the same person.

50. The apparatus of claim 43 or 44, further being devised to generate an electrical current stimulus signal with a randomly selected first amplitude, to maintain said selected amplitude for a period of time and to thereafter randomly select a second amplitude higher than the first amplitude.

51. The apparatus of claim 43 or 44, further being devised to generate an electrical current stimulus signal with a randomly selected first pulse width, to maintain said selected pulse width for a period of time and new higher or pulse width values within predetermined levels, to maintain said selected values for a period of time, and to thereafter randomly select a second pulse width wider than the first pulse width.

52. The apparatus of claim 40, further being devised to increase the stimulation signal starting at a signal level dependent on a previously stored perception threshold.

53. The apparatus of claim 40, further being devised to increase the stimulation signal up to a signal level dependent on a previously stored sensation or tolerance threshold.

54. The apparatus according to any of the claims 40-53, wherein the stimulus induction means (104) comprises a thermal element for emitting a stimulus in the form of thermal

energy.

55. The apparatus of claim 54, wherein the thermal element is a resistive coil or a peltier element.

56. The apparatus of claim 54, wherein the thermal element is a laser, such as an argon laser or carbon dioxide laser.

57. The apparatus of claim 54, further being devised to provide a heat stimulus having an amplitude increasing from an initial temperature preferably in a range of 34 centigrades to a maximum temperature preferably in the range of 60 centigrades, preferably increasing with incremental steps in the range of 0.1 centigrades.

58. The apparatus of claim 57, further being devised to vary the increase rate such that the heat stimulus increases from said initial temperature to said maximum temperature during a time period in the range of 10-60 seconds.

59. Use of an apparatus as recited in any of the claims 1-58 in measuring the level of a sensation.

60. Use of an apparatus as recited in any of the claims 1-58 in measuring the level of a perception.

61. Use of an apparatus as recited in any of the claims 1-58 in measuring the level of an integrated skill.

62. A method of measuring the level of a sensation, perception or integrated skill of a person, comprising the steps of:
delivering to said person a physical stimulus that is comparable with an affective component of said sensation;
registering a first sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation.

63. The method as recited in claim 62, further comprising the step of delivering a pulse width modulated pulsating physical stimulus.

64. The method as recited in claim 62, further comprising the step of delivering a pulsating physical stimulus with a varying pulse width, a fixed frequency and a fixed amplitude.

65. The method as recited in claim 62, further comprising the step of delivering a physical stimulus that is comparable with a sensory component of said sensation.

66. The method as recited in claim 62, further comprising the step of delivering an amplitude modulated pulsating physical stimulus.

67. The method as recited in claim 62, further comprising the step of achieving the physical stimulus by delivering electrical energy to the skin of a human being.

68. The method as recited in claim 67, wherein said electrical energy is voltage controlled.

69. The method as recited in claim 67, wherein said electrical energy is current controlled.

70. The method as recited in claim 67, further comprising the step of delivering electrical energy in the shape of a voltage or a current through a resistance of 0-20 kohm.

71. The method as recited in claim 67, further comprising the step of delivering electrical energy in the shape of a voltage or a current in a sinus wave, preferably having a frequency in the range of 1-100 Hz.

72. The method as recited in claim 67, further comprising the step of delivering a electrical energy in the shape of a voltage or a current in a square wave and/or a triangular wave, preferably having a frequency in the range of 1-100 Hz.

73. The method as recited in claim 67, further comprising the step of varying the amplitude of a pulsating electrical current in the range of 0-100 mA.

74. The method as recited in claim 67, further comprising the step of varying the amplitude of a pulsating electrical current with steps in the range of 0,5 mA.

75. The method as recited in claim 67, further comprising the step of varying the pulse width of a pulsating electrical energy wave in the range of 0-1000 microseconds.

76. The method as recited in claim 67, further comprising the step of varying the pulse width of a pulsating electrical energy wave with steps in the range of 5-10 microseconds.

77. The method as recited in claim 62, further comprising the step of delivering a pulsating physical stimulus with a variable increase rate.

78. The method as recited in claim 77, further comprising the step of delivering said physical stimulus at a first increase rate in a first measurement and at a second increase rate in a subsequent second measurement.

79. The method as recited in claim 77, further comprising the step of delivering said physical stimulus at a first increase rate within a first pulse width range in a first measurement and at a second increase rate within a second pulse width range in a subsequent second measurement.

80. The method as recited in claim 77, further comprising the step of increasing said physical stimulus within a selected time period in a predetermined range of time and said selected time period is different between every two measurements on the same measurement object.

81. The method as recited in claim 79, further comprising the step of increasing the pulse width from about 0 to about 250 microseconds within a first time period between 15 and 40 seconds in said first increase rate, and from about 251 to about 500 microseconds within a second time period between 15 and 40 seconds selected to be different from said first time period.

82. The method as recited in claim 77, further comprising the step of delivering said physical stimulus at a first increase rate within a first amplitude range in a first measurement and at a second increase rate within a second amplitude range in a subsequent second measurement.

83. The method as recited in claim 82, wherein said first and second amplitude ranges are different selections from the range of 0-100 mA, and said first and second increase rates are based on different selections of time periods between 5 and 80 seconds.

84. The method as recited in claim 77, further comprising the step of delivering a physical stimulus with a randomly selected amplitude within a predetermined amplitude range.

85. The method as recited in claim 84, further comprising the step of repeatedly in predetermined time intervals randomly selecting a new amplitude.

86. The method as recited in claim 77, further comprising the step of delivering a physical stimulus with a randomly selected pulse width within a predetermined pulse width range.

87. The method as recited in claim 86, further comprising the step of repeatedly in predetermined time intervals randomly selecting a new pulse width.

88. The method as recited in claim 77, further comprising the step of repeatedly in predetermined time intervals randomly selecting a new increase rate.

89. The method as recited in claim 62, further comprising the step of achieving the physical stimulus by exchanging thermal energy with or inducing thermal energy into the skin of a human being.

90. The method as recited in claim 89, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a sinus wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

91. The method as recited in claim 89, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation in a square wave and/or a triangular wave within a predetermined initial temperature and a predetermined maximum or minimum temperature.

92. The method as recited in claim 89, further comprising the step of delivering a pulsating thermal energy exchange stimulation in the shape of a temperature variation with a pulse width within a pulse width range of 0-1000 microseconds.

93. The method as recited in claim 89, further comprising the step of achieving the physical stimulus by delivering heat to the skin of a human being, preferably increasing the heat stimulus from an initial temperature in the range of 34 centigrades.

94. The method as recited in claim 93, further comprising the step of varying the stimulus increase rate by varying the temperature of the delivered heat from an initial temperature to a predetermined maximum temperature during a time period in the range of 10 to 60 seconds.

95. The method as recited in claim 89, further comprising the step of achieving the physical stimulus by cooling the skin of a human being, preferably increasing the cooling stimulus by decreasing the temperature from an initial temperature in the range of 34 centigrades.

96. The method as recited in claim 95, further comprising the step of varying the stimulus increase rate by varying the temperature of the delivered cooling from an initial temperature to a predetermined minimum temperature during a time period in the range of 10 to 60 seconds.

97. A method for measuring the level of a sensation, perception or integrated skill of a person, comprising the steps of:
selectively delivering to said person a first physical stimulus that is comparable with an affective component of said sensation or a second physical stimulus that is comparable with a sensory component of said sensation;
registering a sensation level value in response to an indication from said person that said physical stimulus corresponds to said sensation;
indicating whether the registered sensation level value is based on said first physical stimulus or said second physical stimulus respectively.

98. The method as recited in claim 97, further comprising the steps of claims 63-96.

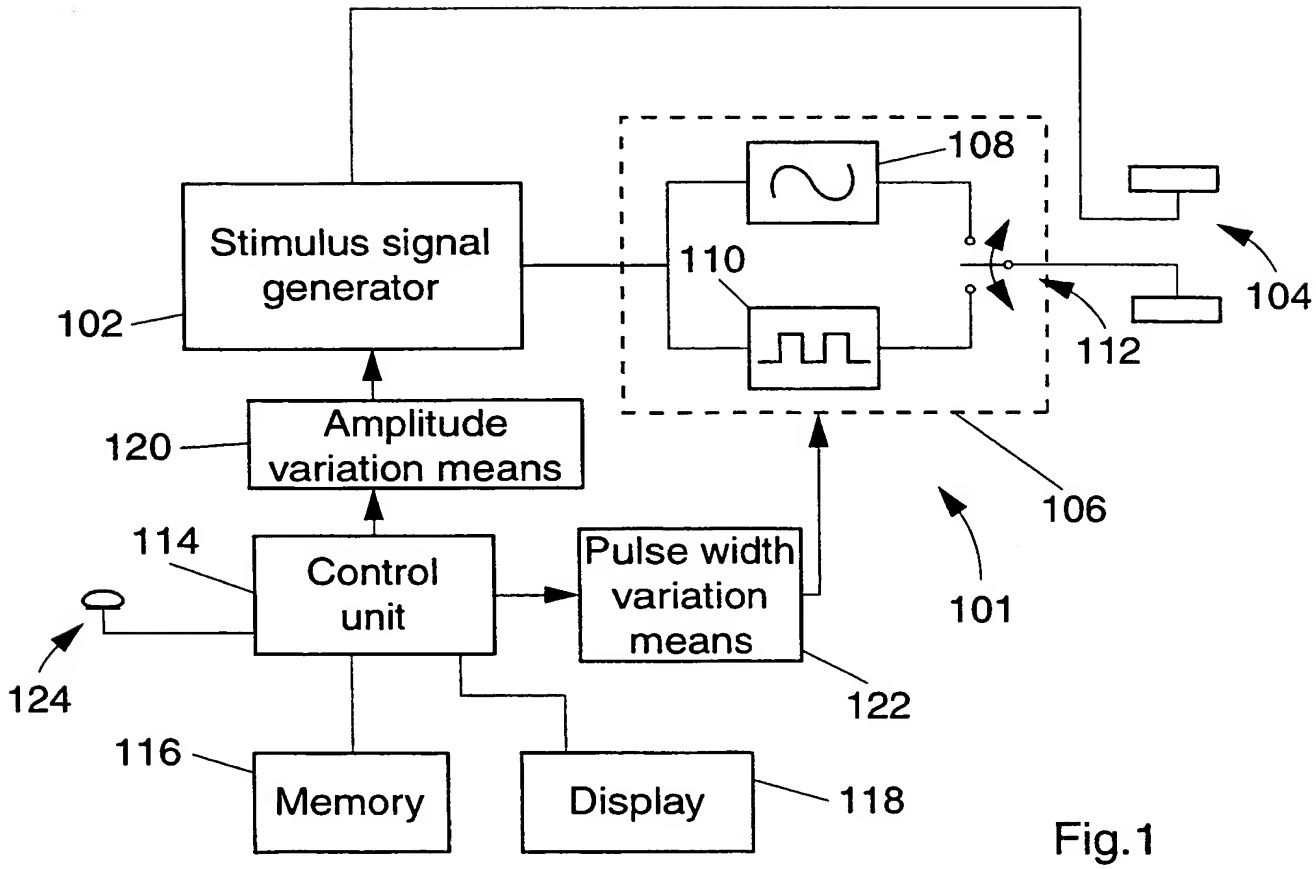

Fig.1

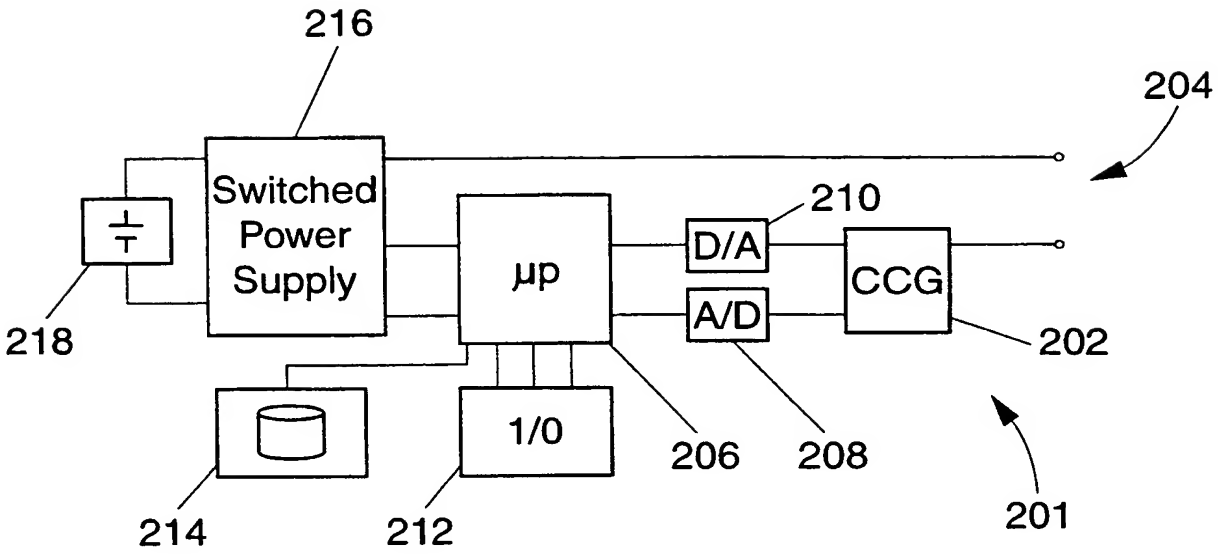

Fig.2

INTERNATIONAL SEARCH REPORT

Ir [redacted]al Application No
PCT/EP 00/08207

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/103

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 191 896 A (E. GAFNI ET AL.) 9 March 1993 (1993-03-09)	1-3, 16-19, 23,24,28
X	column 1, line 38 -column 2, line 18	30,34,36
X	column 2, line 40 -column 3, line 30	38-40, 52-55,59
X	column 3, line 51 -column 4, line 68	60,62-64
X	column 5, line 22 -column 6, line 20	77-80, 84-89, 91,93, 95,97

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
12 December 2000	18/12/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Rieb, K.D.

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INTERNATIONAL SEARCH REPORT

Ir [redacted] l Application No
PCT/EP 00/08207

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 06730 A (J. KATIMS) 27 February 1997 (1997-02-27)	1,4-6, 11,16-19
X	page 7, line 23 -page 8, line 16	23-27,38
X	page 10, line 12 -page 15, line 7	41,44, 49-53
X	page 22, line 21 -page 23, line 23	59,60,62
X	page 25, line 2 -page 26, line 10	65-67, 77-80
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X	page 3, line 2 -page 4, line 14	16-18,28
X	page 4, line 22 -page 5, line 32	32,34,38
X	page 8, line 1 - line 13	41,59, 60, 65-69, 89,95,97

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X	column 1, line 31 -column 2, line 39	32,34, 36,38,41
X	column 3, line 15 - line 52	50,52-55
X	column 4, line 50 -column 5, line 30	59,60, 62,63, 77,84, 89,91, 95,97

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Ir [redacted]al Application No
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Total number of pages: 2

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